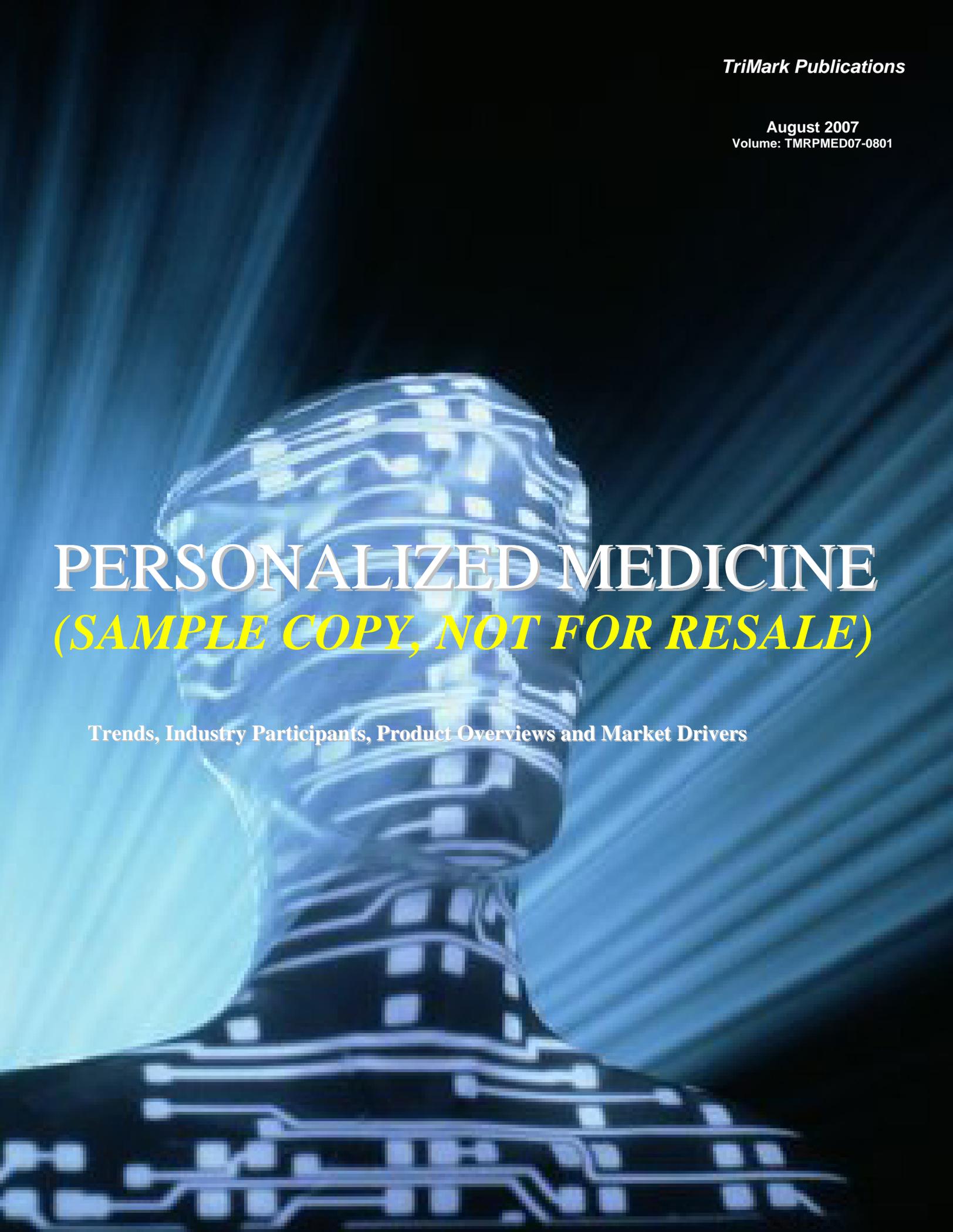


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PERSONALIZED MEDICINE *(SAMPLE COPY, NOT FOR RESALE)*

Trends, Industry Participants, Product Overviews and Market Drivers

TABLE OF CONTENTS

1. Overview	4
1.1 Statement of Report	4
1.2 Scope of this Report	4
1.3 Methodology	5
1.4 Executive Summary	7
2. The Case for Pharmacogenomics and Personalized Medicine: Biology, Approaches, Pipeline and Regulatory Trends	9
2.1 Scope of this Section	9
2.2 Introduction to Pharmacogenomics/Personalized Medicine	9
2.3 The Compelling Case for Personalized Medicine	11
2.4 The Process of Drug Metabolism and Implications for Pharmacogenomics/Personalized Medicine	12
2.5 Examples of Personalized Medicine	16
2.5.1 Herceptin	16
2.5.2 Ziagen	17
2.5.3 Iressa	17
2.5.4 Erbitux	17
2.6 Personalized Medicine Product Pipeline	19
2.7 The Personalized Medicine Coalition	20
2.8 Regulatory Trends and Guidelines in the Personalized Medicine Space	23
2.9 FDA Approved Agendia's MammaPrint® Diagnostic-The First IVDMA to be Approved	24
2.10 A Changing Regulatory Landscape for Personalized Medicine	24
2.11 Patenting Personalized Medicine	26
2.11.1 U.S. Supreme Court Dismisses LabCorp Appeal	27
2.12 The Leading Edge of Personalized Medicine: Specific Examples of Clinical Situations Where Personalized Medicine is Appropriate and Being Used	28
2.12.1 EGFR Assay	28
2.12.2 Individualized Warfarin Therapy	29
2.12.3 UGT1A1 Molecular Assay for Camptosar	29
2.12.4 Response to Gleevec in Gastrointestinal Stromal Tumors	29
2.12.5 LabCorp, ARCA Personalized Medicine Deal for Cardiovascular Diseases	30
2.12.6 Osmetech Licenses Epidauros Biotechnologie AG CYP2D6 Biomarker to Push into Pharmacogenomics	30
3. Pharmacogenomics/Personalized Medicine: Qualitative and Quantitative Market Analysis	37
3.1 Scope of this Section	37
3.2 Market Analysis of Molecular Diagnostics as it Relates to Pharmacogenomics/Personalized Medicine	37
3.3 Snapshot of Diagnostics Industry Structure	41
3.4 The Case for Theranostics (Therapeutic/Companion Diagnostic)	42
3.5 Classification of Diagnostics by Risk	42
3.6 Personalized Medicine Market Analysis-Market Survey Data Characterizing the Qualitative and Quantitative Industry Parameters	43
3.7 Segmentation of the Personalized Medicine Marketplace	44
3.8 Timeline for Impact of Various Segments in Personalized Medicine	45
3.9 Challenges for Personalized Therapeutics Development	47
3.10 Molecular Diagnostics Technology Platforms and Their Impact on Personalized Medicine	48
3.11 Macro Trends in Personalized Medicine	50
3.12 Personalized Medicine: Industry SWOT Analysis	53
4. Company Profiles	55
4.1 Abbott Molecular, Inc./Vysis	55
4.2 Affymetrix, Inc.	56
4.3 Agendia	57
4.4 Celera Diagnostics	58
4.5 Cepheid	58

4.6 Clinical Data, Inc.	59
4.7 Dakocytomation	61
4.8 deCODE Genetics	62
4.9 DNA Direct, Inc.	63
4.10 DxS Ltd.	64
4.11 Exact Sciences Corp.	64
4.12 Exagen Diagnostics, Inc.	65
4.13 Gen-Probe	66
4.14 Genelex Corp.	67
4.15 Gene Logic, Inc.	67
4.16 Genentech, Inc.	69
4.17 Genomic Health, Inc.	69
4.18 Genzyme Genetics	70
4.19 Illumina	72
4.20 Luminex Corporation/Tm Biosciences	73
4.21 Monogram Biosciences	73
4.22 Myriad Genetics, Inc.	75
4.23 Nanogen	76
4.24 Osmetech plc	77
4.25 Perlegen Sciences, Inc.	77
4.26 PGxl Laboratories	78
4.27 Prometheus Laboratories, Inc.	79
4.28 Roche Diagnostics	80
4.29 Siemens Medical Solutions Diagnostics	80
4.30 Target Discovery, Inc.	81
4.31 Third Wave Technologies	82
4.32 Ventana Medical Systems	83
4.33 XDx, Inc.	84
Appendix 1: Qualitative Market Responses	85

LIST OF FIGURES

Figure 2.1: Phase I and II Processes of Drug Metabolism	12
Figure 2.2: Human Phase I Enzymes	13
Figure 2.3: Human Phase II Enzymes	13
Figure 2.4: Hepatic Distribution of Human CYP450	14
Figure 2.5: Relative Contribution of CYP450 Enzymes to Drug Metabolism	14
Figure 2.6: Genetic Components Determine Drug Metabolism	15
Figure 3.1: From Genetic Content to Personalized Medicine	37
Figure 3.2: The Lopsided Remuneration for Diagnostics	38
Figure 3.3: Breakout of the Molecular Diagnostics Marketplace	39
Figure 3.4: Molecular Diagnostics Market Segmentation	40
Figure 3.5: Molecular Diagnostics Market Segmentation by Technology	40
Figure 3.6: Market Survey Respondent Demographics	43
Figure 3.7: Breakout of the Respondent Pool by Affiliation	44
Figure 3.8: Segmentation of the Personalized Medicine Market	44
Figure 3.9: Personalized Medicine Market Drivers	50
Figure 3.10: Challenges in the Personalized Medicine Space	51

LIST OF TABLES

Table 2.1: Personalized Medicine at the Nexus Point	10
Table 2.2: Percentage of Non-Responders in Various Drug Classes	11
Table 2.3: High Profile Drug Withdrawals from the Marketplace	11
Table 2.4: Drug Metabolism Drives Drug Efficacy/Toxicity	16
Table 2.5: Population Frequency of the Various Cytochromes	16
Table 2.6: List of Personalized Medicine Tests	18
Table 2.7: Personalized Medicine Product Pipeline	19
Table 2.8: Marketed Personalized Therapies, 2006	20
Table 2.9: Current Targets, Drugs and Disease Areas Classified by their Clinical Applications	31
Table 3.1: Areas in Personalized Medicine-Timeline of Impact	45
Table 3.2: Impact of Personalized Medicine on Various Therapeutic Areas	47
Table 3.3: Hurdles in Personalized Medicine Development in Various Therapeutic Areas	47
Table 3.4: Various Molecular Diagnostics Technologies: Timeline for Impact	48
Table 3.5: Various Molecular Diagnostics Technologies: Impact on Different Therapeutic Areas in Personalized Medicine	49
Table 3.6: Various Molecular Diagnostics Technologies: Technical Challenges in the Deployment for Personalized Medicine	49
Table 3.7: Market Opportunities in Personalized Medicine	52
Table 3.8: Challenges for Market Adoption of the Various Personalized Medicine Tests	53
Table 3.9: Personalized Medicine Industry SWOT	54

1. Overview

1.1 Statement of Report

The purpose of this report is to describe the specific market segment of the diagnostics market called personalized medicine. This sector includes all of the generally-accepted imaging activities that are currently used in personalized medicine, including pharmacogenomics, genomics and theranostics. It examines associated clinical market segments in which personalized medicine has taken a prominent role including cancer treatment, cardiology and neurology markets.

1.2 Scope of this Report

The main objectives of this study are to:

- Identify viable technology drivers through a comprehensive look at various platform technologies for personalized medicine.
- Obtain a complete understanding of the use of personalized medicine—predictive, screening, prognostic, diagnostic and monitoring—from their basic principles to their applications.
- Discover feasible market opportunities by identification of high-growth applications in different diagnostic areas, with a focus on the biggest and expanding markets for personalized medicine markets.
- Focus on global industry development of personalized medicine through an in-depth analysis of the major world markets for diagnostics, including forecasts for growth.
- Establish the essentials of the personalized medicine market including definitions, processes and trends.

Market figures regarding the current value of the personalized medicine market are taken from the most recently available data of the global medical products industry. This report covers the following categories of personalized medicine:

- Personalized medicine diagnostics.
- Genomics.
- Theranostics.
- Pharmacogenomics.

Analysis of the developing personalized medicine market includes the use of charts and graphs measuring product growth and trends within the marketplace. A survey of potential market users was performed for this study. In addition, a discussion of company-specific information, including sales figures, product pipeline status and R&D trends is provided throughout the report. The report will:

- Assess the personalized medicine market drivers and bottlenecks, from the perspective of the medical and scientific communities.
- Discuss the potential benefits of the personalized medicine market for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the personalized medicine market and analyze the current size and growth of various segments.
- Provide current and forecasted market shares by company.
- Discuss profit/business opportunities segment.
- Provide strategic recommendations for near-term business opportunities.
- Assess current commercial uses of the personalized medicine technology platforms.
- Review the personalized medicine business models.

In the last few years, several multimodal products have been developed in an attempt to combine the advantages of genomics and pharmacology. Multimodal combinations discussed in this examination include pharmacogenomics and theranostics.

These modalities and their unique place in personalized medicine are reviewed in this study. The emphasis in this review is on those companies that are actively developing and marketing personalized medicine technologies. The reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for a detailed discussion of the other important individual market segments that are related to the personalized medicine markets such as the *Bioinformatics Markets*, *Gene Expression Reagents Markets*, *Genomics World Markets*, *Molecular Diagnostics Markets* and *Pharmacogenomic Testing Markets*.

This study reviews the market for personalized medicine in the clinical and research hospital market. It defines the dollar volume of sales, both worldwide and in the U.S., of the market and analyzes the factors that influence the size and the growth of the market segments. The report details market sizes and growth rates for the U.S. and world markets.

The examination discusses activity and trends in the personalized medicine market and goes on to discuss in detail the trends that have developed which have stimulated this market. This analysis also comments in detail on the patterns of information processing in the personalized medicine market. It surveys all of the companies known to be marketing, manufacturing or developing personalized medicine equipment in the U.S. and worldwide. Leading companies are discussed in depth with a section on the history of the company, the product line, business and marketing analysis and a subjective commentary of the position of the company in its market.

Specific objectives of the study include:

- Types of personalized medicine imaging systems on the market.
- Competitive personalized medicine technologies.
- Personalized medicine technologies in R&D.
- Companies competing in the personalized medicine market.
- Company strategies.

1.3 Methodology

The information in this analysis is based upon interviews with sales and marketing professionals of companies in the personalized medicine market. People from virtually every company mentioned were queried, some several times, about their companies' products and marketing strategies as well as their overall thoughts about their industry segment. Information was also obtained from interviews with founders, chief executive officers and vice presidents of some of the companies discussed.

Sources of information for the study were trade association publications and meetings, product brochures and catalogs and company literature. Where the companies under discussion were publicly held, an examination of the annual reports, 10k filings and financial reports were used as the basis of the data reported. Important data sources include the Health for All Database of the World Health Organization (WHO), data published by the statistical office of the European Communities (Eurostat), as well as various health data from the United Nations (UN) and the Organization for Economic Cooperation and Development (OECD). Where possible and practicable, the most recent data available have been used.

The principal author of this report has served as vice president of business development at DiscoverX Corporation. Before DiscoverX, at LJL BioSystems, he served as senior director of business development and played a major role in developing LJL BioSystems' single nucleotide polymorphism (SNP) genotyping business. Subsequent to the acquisition of LJL BioSystems by Molecular Devices Corporation, he ran Molecular Devices' Genomics business. He holds a doctorate in biomedical sciences from the University of Massachusetts Medical School, and completed post-doctoral work at The Rockefeller University in New York and at Harvard Medical School.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. The information set forth in this study was obtained from sources that we believe to be reliable, but we do not guarantee the accuracy, adequacy or completeness of any information, omission or for the results obtained by the use of such information.

Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals with regard to commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this report.

The information in this report is also based upon direct experience with sales and marketing professionals of companies in the point of care instruments and reagents market. People from many companies mentioned in this report were considered thoughtfully about their companies' products and marketing strategies as well as their overall thoughts about their industry segment. The structure of the laboratory facilities was derived from familiarity with scientists and technologists working in these areas.

Primary Sources: TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects and Sector Snapshots that we publish annually. We extract relevant data and analytics from TriMark's research of the past three years as part of this data collection. We also extract qualified data feeds from e-questionnaire responses and primary research responses for this compilation.

Secondary Sources: TriMark uses research publications, journals, magazines, newspapers, news letters, Industry reports, investment research reports, trade and industry association reports, government affiliated trade releases, and other published information as part of our secondary research materials.

The information is then analyzed and translated by the Industry Research Group into a Trimark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations. The report conclusions are verified through intensive interviewing of top ranking companies in the industry.

TriMark Publications Report Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly available databases, proprietary databases, direct meetings and personal interviews with key personnel.
- Formulating a study outline with the assigned writer, including important items:
 - Market and product segment grouping and evaluating their relative significance.
 - Key competitors' evaluations including their relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.
 - End-user research to evaluate analytical significance in market estimation.
 - Supply chain research and analysis to identify any factors affecting the market.
 - New technology platforms and cutting edge applications.
- Identifying the key technology and market trends that drive or affect these markets. Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.
- Launching a combination of primary research activities including two levels of questionnaires, executive-direct focused, company-specific and region-specific communications to qualified and experienced senior executives worldwide.
- Completing a confirmatory primary research assessment of the report's findings with the assistance of Expert Panel Partners from the industry being analyzed.

1.4 Executive Summary

There are a number of benefits of personalized medicine:

- Select optimal therapy.
- Reduce adverse drug reactions (ADRs).
- Increase patient compliance.
- Reduce time, cost and failure rate of clinical trials.
- Rescue drugs that are failing in clinical trials or performing poorly in the market.
- Shift emphasis from reaction to prevention.

Personalized medicine and pharmacogenomics are inextricably linked. Pharmacogenomics is the use of genetic variations (such as SNPs, gene expression variability, or other molecular signatures) to understand and correlate with differential response to pharmaceutical agents (drugs). Pharmacogenomics can be deployed clinically to stratify patients into responders and non-responders and this practice is termed personalized medicine.

For most drugs, there are non-responders, poor-responders, normal responders or hyper-responders. This study presents some high-profile drug withdrawals from the marketplace after launch. A key area of unmet market needs are the ADRs—the fifth leading cause of mortality in the U.S. Personalized medicine seeks to identify and mitigate these ADRs.

The major drug metabolizing enzymes (DMEs) are expressed at the highest levels in the liver. So the liver serves as the most important organ for the metabolic activation and/or clearance/detoxification of drugs. Drug metabolism in the liver, also called biotransformation, serves to control the exposure of the body to potentially harmful substances.

There are a number of examples today where pharmacogenomics/personalized medicine is being practiced in the clinic and an analysis of these examples sheds light on the discipline as its being practiced and the challenges as well as successes encountered to date. TriMark presents the pipeline of personalized medicine-based products that are currently in development. Personalized medicines can be blockbusters.

The current *in vitro* diagnostics (IVD) marketplace is large valued currently at \$ [REDACTED] worldwide, but growing slowly—at a [REDACTED]% compound annual growth rate (CAGR). In contrast, the molecular diagnostics marketplace—a subset of the IVD market—is a much smaller, but more rapidly growing market.

Molecular diagnostics is the detection and characterization of DNA variations or RNA expression from biological samples with the intent to diagnose disease, determine a patient's susceptibility to disease, determine a patient's susceptibility to a given treatment regimen, or determine the prognosis of condition. The market is currently valued at \$ [REDACTED] worldwide, which is growing at a robust CAGR of [REDACTED]% to [REDACTED]%. It is expected that this market will grow to \$ [REDACTED] worldwide by [REDACTED]. The U.S. generates the bulk of sales in this space. A large fraction of molecular diagnostics tests today are polymerase chain reaction (PCR)-based, over time, however, TriMark forecasts that microarray-based tests will grow in abundance.

The emerging applications in molecular diagnostics driving growth are the following:

- Genotyping for identifying drug resistant bacterial strains.
- Disease diagnostics and prognostics:
 - Cancer.
 - Cardiovascular disease.
 - Neurodegenerative disease.
- Therapy selection, patient monitoring/predisposition testing, ADRs.

TriMark presents the theranostic classification of diagnostics into their various classes—I, II and III. It also presents a detailed qualitative and quantitative market analysis of the personalized medicine space based on primary market survey data, which addresses the current segmentation of the personalized medicine marketplace.

As part of its market analysis, we assessed the timeline for impact of various areas in personalized medicine. This is important since this analysis provides benchmarks to the industry as to how far a particular segment in this space is from widespread market acceptance/adoption, and also determines the market potential for a given market segment.

TriMark also assessed the various challenges in the development of personalized medicine-based therapeutics. There are hurdles—technical, legal, regulatory, commercial and socio-political—that need to be addressed in the context of personalized medicine and these hurdles serve as challenges to the industry.

We explore the macro trends and market drivers in the personalized medicine space in order to understand the current market landscape. It has presented a snapshot of the personalized medicine marketplace in both qualitative and quantitative terms. Moreover, the study presents profiles of the relevant companies in this marketplace together with an assessment of the strengths, weaknesses, opportunities and threats (SWOT) of each of these companies. The report also includes analyses of individual companies who are important players in the developing personalized medicine sector.

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